Remarks

Claims 50-76 are pending. These claims were added in a Preliminary Amendment filed on February 25, 2003. Claims have been re-numbered due to an error listing claim 66 for two separate claims. The "second" claim 66 is now claim 67 and the remaining claims are changed accordingly. Dependent claims 69-76 have been amended according to the new claim numbers. Claims 50, 54, 58, 60, 64, and 68 have been amended to read "...a blend comprising poly-3-hydroxybutyrate-co-4-hydroxybutyrate...". Support for the amendments can be found in the specification on page 33, lines 1, 3, and 4. In addition claims 65 and 69 (formerly 68) have been amended for content. Support for the amendments can be found in the specification on pages 33-35, Examples 24-26.

Rejection Under 35 U.S.C. § 112, first paragraph

Previously numbered claims 50-75 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Examiner states that there is no disclosure with respect to the recited P3HB4HB blend. Applicants respectfully submit that this is incorrect. On page 33, line 1 of the specification, Example 24 reads, "Toughness of P3HB-4HB blend". Lines 3 and 4 then describe an example of a blending process. In addition, on page 4, lines 4-7, the specification discloses polymer blends as "compositions comprising **a first biodegradable polymer** comprising a polyhydroxyalkanoate (PHA), **a second biodegradable polymer** different from said first polymer, and one or more oligomeric esters". Then on page 17, lines 20-22, the specification states that the compositions can comprise or consist of **a first biodegradable polymer** comprising a poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3B4HB) and a nucleant.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 65 and 68 (now claim 69) were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Support for the amendments can be found in Examples 24-26. Example 24 recites obtaining tensile test bars by hot pressing granules of the P3HB-4HB blend between two Teflon coated plates and stamping dog-bone bars 4mm wide with a 20mm gauge length. Tensile testing gave elongation at break in the range of between 850% and 1100% as shown by Table 7. Examples 25 and 26 state that the granules obtained as described in Example 24 were made into a film with a width of 70 mm (Example 25) or 55 mm (Example 26) and a thickness of 85 μm (Example 25) or 130 μm (Example 26). Tensile testing on dog-bone samples stamped from the film in the machine direction (4 mm wide, 20 mm gauge length) gave an elongation break in the range of between 560% and 780% (Table 9).

Rejection Under 35 U.S.C. § 103

Claims 50-75 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,688,582 to Nagaoka et al ("Nagaoka"), in view of JP 4-326932, JP 6-336523 or JP 6157878 A2. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Nagaoka

This patent discloses biodegradable filament nonwoven fabrics from polyester compositions. Nagaoka teaches the use of nucleants such as boron nitride and the copolymer of 3HB and 4HB, but not a blend of a copolymer of 3HB and 4HB. In addition, the patent does not disclose that the percentage of 4-hydroxybutyrate (4HB) in the P3HB4HB is between 16% and 99%, and in fact, does not disclose any specific percentages of 4HB at all.

JP 6-336523 and JP 4-326932

These two applications disclose poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB), but do not teach the use of a nucleant such as boron nitride nor a polymer blend. Therefore, the Japanese applications neither disclose nor lead one to a polymer blend

JP 6157878 A2

This application refers to a composition having a high crystallization rate, which is the opposite of a material having a high elongation rate. Crystalline materials are typically brittle and not given to elongation without breaking. The material described in the Japanese reference is prepared by compounding, not blending a copolyester which could be 3HB. The 3-HB makes

up 85-97 mol% and 4-HB makes up the remaining 3-15 mol% of the copolymer. The composition is in the form of particles and further includes 0.5 to 3 wt% BN particles.

This application is representative of the prior art discussed at the top of page 15 of the application, which is characterized by brittleness and lack of elongation properties. This alone differentiates applicants' claimed composition and leads one away from the combination of a PHA copolymer. However, the claims can be further distinguished over the Japanese application because the current application claims a polymer blend. JP 6157878 A2 neither discloses nor leads one to a polymer blend.

The Combination of Nagaoka with JP 6336523, JP 4-326932 or JP 6157878 A2

For a *prima facie* showing of obviousness, there must be some suggestion or motivation to combine the references. Nagaoka disclsoes biodegradable filament nonwoven fabrics from polyester compositions. JP 6-336523 discloses a molded polyester product suited as a medical material or an artificial organ **used in contact with a soft tissue of the living body**. JP 4-326932 teaches a polyester porous film suitable as a medical material through the use of a polymer material having **biocompatibility**. JP 6157878 A2 discloses a resin composition having biodegradability, **biocompatibility** and a high crystallization rate. The three Japanese applications disclose polymer compositions that are biocompatible and intended for use in the living body. It is evident that there is no motivation to combine Nagaoka with these applications, because the nonwoven fabric disclosed by Nagaoka does not have these features. For example, one would not look to the technology disclosed by Nagaoka in order to produce a biocompatible polymer composition that was appropriate for use in a living body.

In summary, neither Nagaoka nor the Japanese applications alone, or in combination, would motivate one of ordinary skill in the art to make a blend comprising poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB), nor would there be a reasonable expectation that if one did make a blend comprising P3HB4HB, that it would have the desirable properties of elongation and tensile strength. Therefore, claims 50-76 are not obvious in view of Nagaoka in combination with JP 6336523, JP 4-326932 or JP 6157878 A2.

Allowance of claims 50-76, as amended, is respectfully solicited.

Respectfully submitted,

Patrea L. Pabst
Reg. No. 31,284

Date: January 9, 2004

HOLLAND & KNIGHT LLP
One Atlantic Center, Suite 2000
1201 West Peachtree Street
Atlanta, Georgia 30309-3400
(404) 817-8473
(404) 817-8588 (Fax)

Certificate of Facsimile Transmission

I hereby certify that this Amendment and Response to Office Action, and any documents referred to as attached therein are being facsimile transmitted on this date to the Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Peggy Bailey

Date: January 9, 2004

1490516_v1